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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

RONALD T. HAMMER REPRESENTATIVE OF THE ESTATE OF RETHA M. SPAIN (DECEASED),

Plaintiff,

v.

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE and MCKESSON CORPORATION,

Defendants.

Case No. CV 08 3394

NOTICE OF REMOVAL AND REMOVAL ACTION UNDER 28 U.S.C. § 1441(B) (DIVERSITY) and 28 U.S.C. § 1441(C) (FEDERAL QUESTION) OF DEFENDANT SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE

TO THE CLERK OF THE COURT:

Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE ("GSK"), hereby removes to this Court the state action described below. Removal is warranted under 28 U.S.C. § 1441 because this is an action over which this Court has original jurisdiction under 28 U.S.C. §§ 1331 and 1332.

I. BACKGROUND

1. On July 10, 2008, Plaintiff Ronald T. Hammer ("Plaintiff"), as representative of the estate of Retha M. Spain (deceased), represented by The Miller Firm of Orange, Virginia,

commenced this action in the Superior Court of the State of California for the County of San Francisco. A true and correct copy of the Complaint in the action is attached as Exhibit "A " to the Declaration of Krista L. Cosner in Support of Notice of Removal and Removal Action under 28 U.S.C. § 1441(b) (Diversity) and 28 U.S.C. § 1441(c) (Federal Question) of Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline (hereinafter "Cosner Decl.").

2. McKesson has not yet been served with Plaintiff's Complaint. Cosner Decl., at ¶ 9.

3. There have been no additional proceedings in the state court action.

4. This is one of many cases that have been filed recently in both federal and state courts across the country involving the prescription drug Avandia®. Cosner Decl., at ¶ 5. Plaintiff's counsel, The Miller Firm, has filed Avandia cases in both state and federal courts, but only in cases filed in California has The Miller Firm named McKesson, or any alleged distributor of Avandia, as defendant. Cosner Decl., at ¶ 6.

5. On October 16, 2007, the Judicial Panel on Multidistrict Litigation ("JPML") issued an order directing that then-pending Avandia-related cases be transferred and coordinated for pretrial proceedings in the United States District Court for the Eastern District of Pennsylvania, before the Honorable Cynthia M. Rufe, pursuant to 28 U.S.C. § 1407. *See* Transfer Order, *In re Avandia Marketing, Sales Practices and Products Liability Litigation*, MDL 1871 (E.D. Pa.) (a true and correct copy of which is attached as Exhibit "B" to Cosner Decl.). Additional Avandia-related cases pending in federal court, which are common to the actions previously transferred to the Eastern District of Pennsylvania and assigned to Judge Rufe, are treated as potential tag-along actions. *See id.*; *see also* Rules 7.4 and 7.5, R.P.J.P.M.L. 199 F.R.D. 425, 435-36 (2001). GSK intends to seek the transfer of this action to that Multidistrict Litigation, *In re Avandia Marketing, Sales Practices and Products Liability Litigation*, MDL 1871, and shortly will provide the JPML with notice of this action pursuant to the procedure for "tag along" actions set forth in the rules of the JPML. Cosner Decl., at ¶ 7.

6. As more fully set forth below, this case is properly removed to this Court pursuant to 28 U.S.C. § 1441 because GSK has satisfied the procedural requirements for removal and this

Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1332.

II. DIVERSITY JURISDICTION AND FORUM DEFENDANT RULE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because this is a civil action in which the amount in controversy exceeds the sum of $75,000, exclusive of costs and interest, and is between citizens of different states.

A. There is Complete Diversity of Citizenship Between Plaintiff and Defendants

8. Plaintiff, Ronald T. Hammer alleges he is a resident of the State of Texas. Accordingly, he is a citizen of the State of Texas. *See* Cosner Decl., Exh. A at ¶ 10.

9. GSK is, and was at the time Plaintiff commenced this action, a corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania, and therefore, is a citizen of Pennsylvania for purposes of determining diversity. *See* 28 U.S.C. § 1332(c)(1); Cosner Decl., at ¶ 8.

10. The remaining named defendant, McKesson, is a Delaware corporation with its principal place of business in San Francisco, California, and therefore is a citizen of California. *See* Cosner Decl., Exh. C at ¶ 3

11. Accordingly, there is complete diversity of citizenship between Plaintiff and defendants.

B. The Amount in Controversy Requirement is Satisfied

12. It is apparent on the face of the Complaint that Plaintiff seeks an amount in controversy in excess of $75,000, exclusive of costs and interest.

13. Plaintiff alleges that, as a result of his decedent's Avandia use, decedent "suffered heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, stroke, and severe injury to the heart leading to cardiac arrest and sustained physical . . . damages." *See* Cosner Decl., Exh. A at ¶ 33.

14. Plaintiff seeks to recover compensatory damages, physical pain and suffering, restitution of the purchase costs and disgorgement of profits, as well as punitive and exemplary damages. *See* Cosner Decl., Exh. A, Prayer for Relief.

15. Punitive damages are included in the calculation of the amount in controversy.

See Bell v. Preferred Life Assurance Society, 320 U.S. 238, 240 (1943).

16. Given the allegations set forth above, the face of the Complaint makes clear that Plaintiff seeks in excess of $75,000, exclusive of interest and costs. *See Simmons v. PCR Tech.*, 209 F. Supp. 2d 1029, 1031 (N.D. Cal. 2002).

C. The Citizenship of McKesson Must be Ignored for Purposes of the Forum Defendant Rule Because McKesson has not been Properly Joined and Served

17. Under 28 U.S.C. § 1441(b), the so-called "forum defendant rule," an action is removable only if none of the parties in interest, *properly joined and served* as defendants, is a citizen of the State in which such action is brought. 28 U.S.C. § 1441(b).

18. McKesson, although a citizen of California, has not yet been served with the Complaint in this case. Cosner Decl., at ¶ 9.

19. Accordingly, because there is complete diversity of citizenship and because no "properly joined and served defendant" is a citizen of this State, it is appropriate that this action be removed to this Court. *See Waldon v. Novartis Pharmaceuticals Corp.*, 2007 U.S. Dist. LEXIS 45809 (N.D. Cal. June 18, 2007); *see also* 28 U.S.C. § 1441(b).

D. The Citizenship of McKesson Must be Ignored Because McKesson is Fraudulently Joined

20. A defendant is fraudulently joined, and its presence in the lawsuit is ignored for purposes of determining the propriety of removal, "if the plaintiff fails to state a cause of action against the resident defendant, and the failure is obvious according to the settled rules of the state." *Morris v. Princess Cruises, Inc.*, 236 F.3d 1061, 1067 (9th Cir. 2001); *see also Hamilton Materials, Inc. v. Dow Chemical Corporation*, 494 F.3d. 1203, 1206 (9th Cir. 2007).

21. McKesson is fraudulently joined because Plaintiff has failed to make any material allegations against it. Plaintiff does not even allege that his decedent ingested Avandia that was distributed by McKesson, compelling the conclusion that Plaintiff has fraudulently joined McKesson in an attempt to defeat diversity jurisdiction. *See Brown v. Allstate Ins. Co.*, 17 F. Supp. 2d 1134, 1137 (S.D. Cal. 1998) (finding in-state defendants fraudulently joined where "no material allegations against [the in-state defendants] are made"); *Lyons v. American Tobacco Co.*, No. Civ. A. 96-0881-BH-S, 1997 U.S. Dist. LEXIS 18365 (S.D. Ala. 1997) (holding that

there is "no better admission of fraudulent joinder of [the resident defendant]" than the failure of plaintiff "to set forth any specific factual allegations" against them). Plaintiff cannot cure this deficiency by simply relying on allegations directed toward "Defendants" or GSK alone.

22. Plaintiff specifically alleges that GSK was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Avandia. *See* Cosner Decl., Exh. A at ¶ 12. Further, plaintiff specifically alleges that Avandia was created and marketed by GSK; that GSK had longstanding knowledge of Avandia-related dangers, which GSK failed to adequately warn and disclose to consumers; that GSK concealed, suppressed and failed to disclose these referenced dangers; that GSK has represented and has continued to represent that it manufactures and/or sells safe and dependable pharmaceuticals; that GSK has failed to adequately warn or inform consumers, such as Plaintiff's decedent or Plaintiff's decedent's prescribing physicians of known defects in Avandia; and that as a result of GSK's omissions and/or misrepresentations, Plaintiff's decedent ingested Avandia. *See id.* at ¶¶ 21, 25-27, 30, 32-33.

23. Plaintiff also claims, however, that McKesson "packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or inform users regarding the risks pertaining to, and assuaged concerns about [] Avandia." *See id.* at ¶ 19. These allegations are inconsistent and contradictory, and courts have frequently viewed such inconsistencies as evidence of fraudulent joinder. *See Baisden v. Bayer Corp.*, 275 F. Supp. 2d 759, 762-63 (S.D. W.Va. 2003).

24. Plaintiff asserts claims of (1) negligence; (2) negligent failure to adequately warn; (3) negligence per se; (4) negligent misrepresentation; (5) breach of express warranty; (6) breach of implied warranty; (7) strict products liability—defective design; (8) strict products liability—manufacturing and design defect; (9) strict products liability—failure to adequately warn; (10) fraudulent misrepresentation; (11) violations of California Unfair Trade Practices and Consumer Protection Law; (12) unjust enrichment; (13) wrongful death; (14) survival action; and (15) punitive damages. In these allegations, Plaintiff avers that collectively, "Defendants" or "Defendants GSK and McKesson," defectively designed and manufactured the product;

concealed knowledge of unreasonably dangerous risks associated with the product; failed to conduct adequate and sufficient pre-clinical testing and post-marketing surveillance of the product; failed to provide FDA with complete and adequate information regarding the product; failed to warn consumers and/or their health care providers of certain risks associated with the product; failed to utilize adequate and non-misleading labeling; and made affirmative misrepresentations and omissions regarding the risks associated with taking Avandia. All of these claims are substantively based on the design and manufacture of the product, failure to warn, fraudulent concealment, and inadequate pre-clinical testing and post-marketing surveillance. As a wholesale distributor of Avandia, McKesson played no role in its testing, marketing, or advertising. All McKesson did was pass along unopened boxes of Avandia, in unadulterated form, to hospitals and other businesses in the healthcare industry. *See* Cosner Decl., Exh. C at ¶¶ 6-7.[1]

25. Further, based on the "learned intermediary" doctrine, McKesson bore no duty to warn Plaintiff. The "learned intermediary" doctrine, the foundation of prescription drug product liability law, provides that the duty to warn about a drug's risks runs from the manufacturer to the physician (the "learned intermediary"), and then from the physician to the patient. *See Brown v. Superior Court (Abbott Labs.)*, 44 Cal. 3d 1049, 1061-62, n.9 (1988); *Carlin v. Superior Court (Upjohn Co.)*, 13 Cal. 4th 1104, 1116 (1996). It is the physician, and only the physician, who is charged with prescribing the appropriate drug and communicating the relevant risks to the patient. *See Brown*, 44 Cal. 3d at 1061-62.

26. GSK and the FDA prepared the information to be included with the prescription drug, Avandia, with the FDA having final approval of the information that could be presented. Once the FDA has determined the form and content of the information, it is a violation of federal

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[1] The Declaration of McKesson's representative, Greg Yonko, may be considered by the Court in determining whether McKesson is fraudulently joined. *Maffei v. Allstate California Ins. Co.*, 412 F. Supp. 2d 1049 (E.D. Cal. 2006) ("The court may pierce the pleadings, consider the entire record, and determine the basis of joinder by any means available.") (citing *Lewis v. Time, Inc.*, 83 F.R.D. 455 (E.D. Cal. 1979) ("[I]t is well settled that upon allegations of fraudulent joinder . . . federal courts may look beyond the pleadings to determine if the joinder . . . is a sham or fraudulent device to prevent removal")); *see also Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1318-19 (9th Cir. 1998) (evidence may be presented by the removing party that there is no factual basis for the claims pleaded against the local defendant).

law to augment the information. *See* 21 U.S.C. § 331(k) (prohibiting drug manufacturers and distributors from causing the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling" of an FDA-approved drug held for sale); *Brown*, 44 Cal. 3d at 1069 n.12 (noting that the FDA regulates the testing, manufacturing, and marketing of drugs, including the content of their warning labels). Therefore, any safety and warning information McKesson had about Avandia would have come from GSK in the form of FDA-approved packaging and labeling. McKesson could not change the labeling it was given by GSK as approved by the FDA without violating federal law. No duty can be found where it requires a party to violate the law to fulfill it.

27. As such, given the lack of a causal connection between the injuries alleged by Plaintiff and McKesson's conduct, as well as the absence of any legal or factual basis for Plaintiff's claims against McKesson, McKesson's joinder is fraudulent and its citizenship should be ignored for purposes of determining the propriety of removal.

III. FEDERAL QUESTION JURISDICTION

28. This Court has federal question jurisdiction over Plaintiff's claims under 28 U.S.C. § 1331 and the principles set forth in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 125 S. Ct. 2363 (2005).

29. As more fully explained below, Plaintiff has made violations of federal law critical elements of several of his claims.

A. Plaintiff's Claims Require Construction and Application of the FDCA and its Implementing Regulations

30. Count III of Plaintiff's Complaint, "Negligence Per Se," explicitly alleges that defendants violated federal law. Plaintiff claims, *inter alia*, that "[d]efendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301 *et seq.*, related amendments and codes and federal regulations provided thereunder, and other applicable laws, statutes, and regulations." *See* Cosner Decl., Exh. A at ¶ 54.

31. Plaintiff further claims that "[d]efendants' acts constituted an adulteration and/or misunderstanding [sic] as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C.

§ 331 . . . ." *See* Cosner Decl., Exh. A at ¶ 56.

32. Moreover, Count II of Plaintiff's Complaint, "Negligent Failure to Adequately Warn," and Count IX, "Strict Products Liability—Failure to Adequately Warn," also require construction and application of the FDCA and implementing federal regulations, which govern approval of prescription drugs and regulate prescription drug manufacturers' public and promotional statements, including all aspects of warnings and labeling.

33. As a currently-marketed prescription drug, Avandia is subject to extensive regulation by the FDA. The FDCA requires the FDA to ensure that "drugs are safe and effective" for their intended uses, 21 U.S.C. § 393(b)(2)(B), in part by "promptly and officially reviewing clinical research and taking appropriate action on the marketing of regulated products." 21 U.S.C. § 393(b)(1). The Secretary of the FDA has the authority to promulgate regulations to enforce the FDCA, which are codified in the *Code of Federal Regulations*, 21 C.F.R. § 200, *et seq*. *See* 21 U.S.C. § 371(a).

34. To accomplish its purpose, the FDA maintains a Center for Drug Evaluation and Research (the "CDER"). The CDER regulates pharmaceutical companies' development, testing and research, and manufacture of drugs. The CDER examines data generated by these companies to conduct a risk/benefit analysis and make an approval decision. The CDER also ensures truthful advertising for prescription drugs, in part by approving Package Inserts that properly outline benefit and risk information. Once drugs are marketed, the CDER continues to monitor them for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. In short, the CDER evaluates and monitors the effectiveness and safety of prescription drugs. *See* http://www.fda.gov/cder/about/faq/default.htm.

35. Promotional communications to physicians about Avandia are contained within, and restricted by, warning, labeling, and promotional materials, such as the Package Insert, that are approved and monitored by the FDA to ensure the provision of accurate information about the drug's respective risks and benefits. Under federal regulations, even claims in promotional labeling or advertising must be consistent with approved labeling. 21 C.F.R. § 202.1(e)(4)

(2005).

36. The FDA's responsibility to regulate prescription drugs sold in the United States, and to enforce laws with respect to such drugs, inclusive of the precise content and format of prescription drug labeling (*e.g.*, the instructions, warning, precautions, adverse reaction information provided by manufacturers, and marketing materials), is plenary and exclusive. *See* 21 U.S.C. § 301, *et seq.*

37. Plaintiff has explicitly alleged violations of federal law in his "Negligence Per Se" claim, and has made alleged violations of federal law a critical element of his "Negligent Failure to Adequately Warn" and "Strict Products Liability—Failure to Adequately Warn" claims. Accordingly, Plaintiff's claims necessarily raise substantial federal questions by requiring the Court to construe and apply the FDCA and its implementing regulations.

B. Federal Control of Drug Labeling and Warning

38. On January 24, 2006, the FDA announced a rule that includes a detailed and emphatic statement of the FDA's intention that its regulation and approval of prescription drug labeling preempt most state law claims related to the adequacy of prescription drug warnings because such claims frustrate "the full objectives of the Federal law." *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("FDA believes that under existing preemption principles, FDA approval of labeling under the act. . . . preempts conflicting or contrary State law."); *see also In re Bextra and Celebrex Marketing*, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006) (Celebrex decision); *In re Bextra and Celebrex Marketing*, 2006 WL 2472484 (N.D. Cal. Aug. 24, 2006) (Bextra decision).

39. Plaintiff alleges that Defendants failed to disclose certain risks of Avandia. *See, e.g.*, Cosner Decl., Exh. A at ¶¶ 25-27. This allegation necessarily requires Plaintiff to establish that the FDA, which has exclusive jurisdiction over the labeling of drugs, would have approved the warning the Plaintiff alleges should have been given.

40. Accordingly, there is a substantial federal question with respect to whether Plaintiff can claim that GSK violated state law in light of the FDA's control of Avandia's labeling

and warning and its position on conflict preemption.

C. The Federal Interest in Providing a Forum

41. The federal government has a strong interest in having a federal court decide several of the issues in this case. Among these issues are:

a. whether any conduct of GSK violated any federal laws or regulations related to the labeling and marketing of Avandia; and

b. whether the FDA-approved Avandia label was false and misleading, as alleged by Plaintiff, and whether a state may impose liability on GSK for not providing more information regarding alleged risks, as Plaintiff contends GSK should have done.

42. Plaintiff's claims may be vindicated or defeated only by construction of federal statutes and regulations. The availability of a federal forum to protect the important federal interests at issue is therefore consistent with *Grable*, and determination by a federal court of the substantial and disputed federal issues that lie at the heart of this case would not "disturb any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 125 S. Ct. at 2368.

IV. CONFORMANCE WITH PROCEDURAL REQUIREMENTS

43. This Court has jurisdiction over this matter based on federal question and diversity of citizenship, and the present lawsuit may be removed from the Superior Court of the State of California for the County of San Francisco, and brought before the United States District Court for the Northern District of California pursuant to 28 U.S.C. §§ 1331, 1332 and 1441.

44. Plaintiff filed this action on July 10, 2008. *See* Cosner Decl., Exh. A. McKesson has not been served with the Plaintiff's Complaint. *See* Cosner Decl., at ¶ 9. Therefore, this Removal on July 14, 2008 has been timely filed. *See* 28 U.S.C. § 1446(b).

45. Since McKesson has not been "properly joined and served" at the time of filing this Removal, GSK is entitled to removal under the plain language of 28 U.S.C. § 1441(b). *See Waldon*, 2007 U.S. Dist. LEXIS 45809 (N.D. Cal. June 18, 2007); Cosner Decl., at ¶ 9.

46. McKesson's consent to remove is not necessary because it is fraudulently joined.

See, e.g., Emrich v. Touche Ross & Co., 846 F.2d 1190, 1193 n.1 (9th Cir. 1988).

47. The United States District Court for the Northern District of California is the federal judicial district encompassing the Superior Court of the State of California for the County of San Francisco, where this suit was originally filed. Venue therefore is proper in this district under 28 U.S.C. § 1441(a).

48. Pursuant to the provisions of 28 U.S.C § 1446(d), GSK will promptly file a copy of this Notice of Removal with the clerk of the Superior Court of the State of California for the County of San Francisco, where this suit was originally filed.

49. Defendant reserves the right to amend or supplement this Notice of Removal.

WHEREFORE, GSK respectfully removes this action from the Superior Court of the State of California for the County of San Francisco to the United States District Court for the Northern District of California, pursuant to 28 U.S.C. § 1441.

Dated: July 14, 2008

DRINKER BIDDLE & REATH LLP

By: _____
Krista L. Cosner

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